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# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

· · · · · · · · · · · · · · · · · · ·	Application No.	Applicant(s)				
	10/626,028	MCDONALD ET AL.				
Office Action Summary	Examiner	Art Unit				
	Damon Conover	2624				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNI 36(a). In no event, however, may a vill apply and will expire SIX (6) MON cause the application to become Al	CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 24 Ju	<u>ıly 2003</u> .					
2a) This action is <b>FINAL</b> . 2b) ⊠ This	action is non-final.					
3) Since this application is in condition for allowar	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-20 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-20 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on 24 July 2003 is/are: a) Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	☑ accepted or b)☐ object drawing(s) be held in abeyation is required if the drawing	nce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date 12/29/03.</li> </ol>	Paper No(	Summary (PTO-413) s)/Mail Date nformal Patent Application 				

Art Unit: 2624

### **DETAILED ACTION**

### Specification

1. Claim 20 is objected to because of the following informalities: it is not clear from what claim it depends. The examiner has assumed that it depends from claim 11.

Appropriate correction is required.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-2, 4, 6, 10-12, 14, 16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al. (U.S. Patent 5,570,430) (hereinafter Sheehan '430) and Sheehan et al. (U.S. Patent 5,889,524) (hereinafter Sheehan '524) in view of Sandrik et al. (U.S. Patent 4,852,139).

With respect to claim 1, Sheehan '430 discloses a system and method for using a sequence of image frames made during at least one cardiac cycle to determine the contour of a chamber in an in vivo heart (column 3, lines 21-25). Sheehan '430 describes that digital image data may be acquired using a contrast-enhanced left ventriculogram and that the images are typically used to determine tracings of the endocardial boundary at end diastole and end systole (column 1, lines 17-48). The pixels in each image frame are classified by indicating whether the pixels are more likely to be inside or outside the contour of the chamber to determine an initial estimate of the

Art Unit: 2624

contour (extracting boundary pixels) (column 3, lines 29-32). The system uses training data derived by manually analyzing contours of a corresponding chamber in a plurality of other hearts (training a pixel classifier) (column 3, lines 33-35). By processing the sequence of digital image frames of the left ventricle that have been made over at least one cardiac cycle, the system automatically determines the contour of the endocardial surface of the left ventricle at multiple times during the cardiac cycle (indicating the contour of the left ventricle for the end diastolic and end systolic portions of the cardiac cycle) (column 6, lines 39-44).

Sheehan '430 does not describe calculating a pre-determined set of feature images from the sequence of image frames, the end diastolic and end systolic image frames, and anatomic landmarks.

Sheehan '524 discloses a method and system for reconstructing the surface of a heart using image data, the contours of the left ventricle, and of related anatomic landmarks or features (column 5, 3-11). Sheehan '524 describes that data for the heart are acquired by imaging the heart in multiple planes whose location and orientation in three-dimensional space are known. The borders of the left ventricle and other anatomic structures, features, or landmarks are traced at end diastole and end systole, producing an input data set that includes points representing the locations of anatomic landmarks (column 7, lines 33-41). Based on this knowledge of the cardiac structure, a set of subdivided control meshes (set of feature images) is produced (column 7, lines 42-56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the control mesh (feature image) calculating step, as taught by

Art Unit: 2624

Sheehan '524, in the left ventricle contour determination method of Sheehan '430, in order to generate a three-dimensional representation of the heart (Sheehan '524, column 5, lines 25-33).

Neither Sheehan '430, nor Sheehan '524 describe a de-flickering step.

Sandrik et al. discloses a method and apparatus for reducing flicker of an x-ray image on a video (column 1, lines 9-12). The flicker effect is created by a difference in intensity between video fields (column 1, lines 60-61). Sandrik et al. describe that the problem of the flicker effect is overcome by modifying the gain of the system to a level such that the image present on the video monitor has the same intensity as the image presented during the initial scan of the target (column 3, lines 21-26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the de-flickering step, as taught by Sandrik et al., in the left ventricle contour determination method of Sheehan '430 and Sheehan '524, in order to eliminate the flicker effect (Sandrik et al., column 1, line 59 – column 2, line 28).

With respect to claim 2, Sheehan '430 describe a step of masking the ventriculogram image frames with a mask that substantially excludes pixels in the ventriculogram image frames that are outside the left ventricle (column 2, lines 31-35).

With respect to claims 4 and 6, Sheehan '430 shows in Figure 4 a first stage classifier 122 for extracting the region-of-interest using a feature vector and a second stage classifier 128 for identifying end systole from normalized region-of-interest histograms. The two classifiers operate sequentially (column 9, line 38 – column 11, line 63). Although Figure 4 only shows the identification of an end systole frame, Sheehan

Art Unit: 2624

'430 describes that image frames for a systole portion and for a diastole portion of the cardiac cycle are processed separately to determine the contour of the change of the chamber of the in vivo heart. Therefore the identification of an end diastole frame would be accomplished using the same method shown in Figure 4, but with a separate set of classifiers (column 4, lines 35-38).

With respect to claim 10, as discussed above, Sheehan '430 discloses a system and method for using a sequence of image frames made during at least one cardiac cycle to determine the contour of a chamber in an in vivo heart (column 3, lines 21-25).

Sheehan '430 does not describe producing a reconstructed border of the left ventricle for end diastole and end systole by fitting a subdivided polygon with the end diastolic and end systolic image frames.

As discussed above, Sheehan '524 discloses a method and system for reconstructing the surface of a heart using image data, the contours of the left ventricle, and of related anatomic landmarks or features (column 5, 3-11). Sheehan '524 describes that data for the heart are acquired by imaging the heart in multiple planes whose location and orientation in three-dimensional space are known. The borders of the left ventricle and other anatomic structures, features, or landmarks are traced at end diastole and end systole, producing an input data set that includes points representing the locations of anatomic landmarks (column 7, lines 33-41). Based on this knowledge of the cardiac structure, a set of subdivided control meshes comprising a plurality of polygons is produced which is then applied to the data for an individual's heart. The

Art Unit: 2624

subdivided mesh is rigidly aligned to the input data set defining the traced borders and location of the anatomic landmarks. The vertices of the embedded subdivided mesh are then adjusted to optimize the fit of the aligned subdivided control mesh to the input data which yields the reconstructed surface (Figure 1 and column 7, lines 28-63).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the control mesh calculating step, as taught by Sheehan '524, in the left ventricle contour determination method of Sheehan '430, in order to generate a three-dimensional representation of the heart (Sheehan '524, column 5, lines 25-33).

With respect to claims 11-12, 14, 16, and 20, the "system for automatically determining a contour of a left ventricle of a heart" corresponds to the "method for automatically determining a contour of a left ventricle of a heart" of claims 1-2, 4, 6, and 10. The discussion is the same as is addressed above. Sheehan '430 further describes that the digital image data and instructions are stored in an image data storage device 32 (nonvolatile storage). The contour of the left ventricle in an image frame that is automatically determined by the method is presented to the user on a display 40. Both the image data storage device 32 and the display 40 are coupled to processor 34 (column 6, lines 45-64).

Application/Control Number: 10/626,028 Page 7

Art Unit: 2624

3. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan '430, Sheehan '524, and Sandrik et al. as applied to claims 1-2, 4, 6, 10-12, 14, 16, and 20 above, and further in view of the article "Hyperspectral Techniques in Analysis of Oral Dosage Forms" by Sara J. Hamilton, Amanda E. Lowell, and Robert A. Lodder.

With respect to claim 3, as discussed above, Sheehan '430 discloses a system and method for using a sequence of image frames made during at least one cardiac cycle to determine the contour of a chamber in an in vivo heart (column 3, lines 21-25). Sheehan '430 describes a step of masking the gray-level ventriculogram image frames with a mask that substantially excludes pixels in the ventriculogram image frames that are outside the left ventricle (column 2, lines 31-35). As discussed above, Sheehan '524 discloses a method and system for reconstructing the surface of a heart using image data, the contours of the left ventricle, and of related anatomic landmarks or features (column 5, 3-11). As discussed above, Sandrik et al. discloses a method and apparatus for reducing flicker of an x-ray image on a video (column 1, lines 9-12). The flicker effect is created by a difference in intensity between video fields (column 1, lines 60-61). Sandrik et al. describe that the problem of the flicker effect is overcome by modifying the gain of the system to a level such that the image present on the video monitor has the same intensity as the image presented during the initial scan of the target (column 3, lines 21-26).

Neither Sheehan '430, Sheehan '524, nor Sandrik et al. describe that the deflickering step includes using repeated median regression.

Art Unit: 2624

Hamilton et al. discuss maintaining adequate signal-to-noise ratios in

hyperspectral imaging techniques (abstract). Hamilton et al. describe that part of the signal\noise problem arises from flickering pixels (page 564, section 3). Hamilton et al.

go on to describe that median regression is one method for improving the signal-to-

noise ratio (page 564, section 3.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use median regression for de-flickering, as taught by Hamilton et al., in the left ventricle contour determination method of Sheehan '430, Sheehan '524, and Sandrik et al., in order to improve the signal-to-noise ratio (Hamilton et al., page 564, section 3.1).

With respect to claim 13, the "system for automatically determining a contour of a left ventricle of a heart" corresponds to the "method for automatically determining a contour of a left ventricle of a heart" of claim 3. The discussion is the same as is addressed above. Sheehan '430 further describes that the digital image data and instructions are stored in an image data storage device 32 (nonvolatile storage). The contour of the left ventricle in an image frame that is automatically determined by the method is presented to the user on a display 40. Both the image data storage device 32 and the display 40 are coupled to processor 34 (column 6, lines 45-64).

Application/Control Number: 10/626,028 Page 9

Art Unit: 2624

4. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan '430, Sheehan '524, and Sandrik et al. as applied to claims 1-2, 4, 6, 10-12, 14, 16, and 20 above, and further in view of Reeves et al. (U.S. Patent Publication 2003/0095696).

With respect to claim 5, as discussed above, Sheehan '430 discloses a system and method for using a sequence of image frames made during at least one cardiac cycle to determine the contour of a chamber in an in vivo heart (column 3, lines 21-25). Sheehan '430 shows in Figure 4 a first stage classifier 122 for extracting the region-of-interest using a feature vector and a second stage classifier 128 for identifying end systole from normalized region-of-interest histograms. The two classifiers operate sequentially (column 9, line 38 – column 11, line 63). As discussed above, Sheehan '524 discloses a method and system for reconstructing the surface of a heart using image data, the contours of the left ventricle, and of related anatomic landmarks or features (column 5, 3-11). As discussed above, Sandrik et al. discloses a method and apparatus for reducing flicker of an x-ray image on a video (column 1, lines 9-12).

Neither Sheehan '430, Sheehan '524, nor Sandrik et al. describe that the output of the first stage classifier is blurred before being input to the second stage classifier.

Reeves et al. disclose methods for detection and feature extraction for size characterization of medical images (abstract). Reeves et al. describe that a mean filter can be used blur an x-ray image and reduce the effect of noise before the image is segmented (paragraph 113).

Art Unit: 2624

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the mean filter, as taught by Reeves et al., prior to the final classification step in the left ventricle contour determination method of Sheehan '430, Sheehan '524, and Sandrik et al., in order to generate a clean image before the image is segmented (Reeves et al., paragraph 113).

With respect to claim 15, the "system for automatically determining a contour of a left ventricle of a heart" corresponds to the "method for automatically determining a contour of a left ventricle of a heart" of claim 5. The discussion is the same as is addressed above. Sheehan '430 further describes that the digital image data and instructions are stored in an image data storage device 32 (nonvolatile storage). The contour of the left ventricle in an image frame that is automatically determined by the method is presented to the user on a display 40. Both the image data storage device 32 and the display 40 are coupled to processor 34 (column 6, lines 45-64).

5. Claims 7-8 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan '430, Sheehan '524, and Sandrik et al. as applied to claims 1-2, 4, 6, 10-12, 14, 16, and 20 above, and further in view of Freund (U.S. Patent 6,456,993) and the article "Experiments with a New Boosting Algorithm" by Yoav Freund and Robert E. Schapire.

With respect to claims 7-8, as discussed above, Sheehan '430 discloses a system and method for using a sequence of image frames made during at least one cardiac cycle to determine the contour of a chamber in an in vivo heart (column 3, lines 21-25). Sheehan '430 shows in Figure 4 a first stage classifier 122 for extracting the

Art Unit: 2624

region-of-interest using a feature vector and a second stage classifier 128 for identifying end systole from normalized region-of-interest histograms. The two classifiers operate sequentially (column 9, line 38 – column 11, line 63). As discussed above, Sheehan '524 discloses a method and system for reconstructing the surface of a heart using image data, the contours of the left ventricle, and of related anatomic landmarks or features (column 5, 3-11). As discussed above, Sandrik et al. discloses a method and apparatus for reducing flicker of an x-ray image on a video (column 1, lines 9-12).

Sheehan '430 describe that a Bayesian classification approach is used to classify each pixel as a function of its location and its gray scale value (column 8, lines 7-9).

Neither Sheehan '430, Sheehan '524, nor Sandrik et al. describe that the end diastolic and end systolic classifiers are decision trees.

Freund discloses methods and systems for creating and modifying general alternating decision tree classifiers (column 1, lines 43-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use decision tree classifiers, as taught by Freund, in place of Bayesian classification used in the left ventricle contour determination method of Sheehan '430, Sheehan '524, and Sandrik et al., in order to reduce the classifier complexity (Freund, column 1, lines 33-40).

Freund describes that AdaBoost is a known boosting technique (column 1, lines 22-32), but neither Sheehan '430, Sheehan '524, Sandrik et al., nor Freund specifically describe the AdaBoost.M1 algorithm.

Freund et al. describe the AdaBoost.M1 algorithm (Figure 1 and section 2.1).

Art Unit: 2624

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the AdaBoost.M1 algorithm, as taught by Freund et al., in the left ventricle contour determination method of Sheehan '430, Sheehan '524, Sandrik et al., and Freund in order to improve the performance of the learning algorithm (Freund et al., section 5).

With respect to claims 17-18, the "system for automatically determining a contour of a left ventricle of a heart" corresponds to the "method for automatically determining a contour of a left ventricle of a heart" of claims 7-8. The discussion is the same as is addressed above. Sheehan '430 further describes that the digital image data and instructions are stored in an image data storage device 32 (nonvolatile storage). The contour of the left ventricle in an image frame that is automatically determined by the method is presented to the user on a display 40. Both the image data storage device 32 and the display 40 are coupled to processor 34 (column 6, lines 45-64).

6. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan '430, Sheehan '524, and Sandrik et al. as applied to claims 1-2, 4, 6, 10-12, 14, 16, and 20 above, and further in view of Johnson et al. (U.S. Patent 6,993,170).

With respect to claim 9, as discussed above, Sheehan '430 discloses a system and method for using a sequence of image frames made during at least one cardiac cycle to determine the contour of a chamber in an in vivo heart (column 3, lines 21-25). As discussed above, Sheehan '524 discloses a method and system for reconstructing the surface of a heart using image data, the contours of the left ventricle, and of related anatomic landmarks or features (column 5, 3-11). As discussed above, Sandrik et al.

Art Unit: 2624

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discloses a method and apparatus for reducing flicker of an x-ray image on a video (column 1, lines 9-12).

Neither Sheehan '430, Sheehan '524, nor Sandrik et al. describe that boundary pixels are determined using dilation and erosion.

Johnson et al. disclose a method to facilitate visualization of a feature in a tissue specimen using mathematical algorithms to construct boundaries of the feature (column 1, line 66 – column 2, line 5). Johnson et al. describe that these mathematical algorithms include dilation (adding pixels to the boundary of an object) and erosion (removing pixels to the boundary of an object) (column 2, lines 29-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the dilation and erosion algorithms, as taught by Johnson et al., in the left ventricle contour determination method of Sheehan '430, Sheehan '524, and Sandrik et al., in order to improve boundary detection (Johnson et al., column 2, lines 29-40).

With respect to claim 19, the "system for automatically determining a contour of a left ventricle of a heart" corresponds to the "method for automatically determining a contour of a left ventricle of a heart" of claim 19. The discussion is the same as is addressed above. Sheehan '430 further describes that the digital image data and instructions are stored in an image data storage device 32 (nonvolatile storage). The contour of the left ventricle in an image frame that is automatically determined by the method is presented to the user on a display 40. Both the image data storage device 32 and the display 40 are coupled to processor 34 (column 6, lines 45-64).

Art Unit: 2624

#### Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sheehan et al. (U.S. Patent 5,601,084) and Sheehan et al. (U.S. Patent 5,435,310) disclose a method for imaging and three-dimensional modeling portions of the heart (abstract).

Sheehan et al. (U.S. Patent 6,106,466) disclose a method for defining a threedimensional surface of at least a portion of a patient's heart (abstract).

Han et al. (U.S. Patent 5,457,754) disclose an improved method for extracting the edge boundary of an object presented as an ultrasound video image (abstract).

Makram-Ebeid et al. (U.S. Patent 5,617,459) disclose a method for processing images in order to automatically detect key pixels situated on the contour of an object in an initial image(abstract).

Gerard et al. (U.S. Patent 6,366,684) disclose a method for processing an intension image formed of points representing an object, including steps for automatically supplying points so as to determine a minimum path representing the object contour (abstract).

Fletcher et al. (U.S. Patent 4,101961) disclose a real-time contour detector and data acquisition system for an angiographic apparatus (abstract).

Oe (U.S. Patent 5,065,435) discloses a method for analyzing ventricular function using end diastolic and end systolic contour image data (abstract).

Art Unit: 2624

Oe (U.S. Patent 4,936,311) discloses a method of analyzing regional ventricular

function utilizing centerline methods capable of producing sufficiently natural results in

the vicinity of the apex (abstract).

Wischermann (US Patent Publication 2003/0147011) discloses a device for reducing flicker disturbances in a video signal using a temporal median filter (abstract).

In the article "Extraction of the Contours of Left Ventricular Cavity, According with Those Traced by Medical Doctors, from Left Ventriculograms using a Neural Edge Detector", Kenji Suzuki, Isao Horiba, Noboru Sugie, and Michio Nanki propose a novel edge detector using a multilayer neural network to extract the contours according to those traced by medical doctors (abstract).

In the article "Automatic Contour Definition on Left Ventriculograms by Image Evidence and a Multiple Template-Based Model", Patrice Lilly, Janice Jenkins, and Patrick Bourdillon describe a new algorithm which exploits digital image processing and pattern recognition methods for automated definition of left ventricular contours (abstract).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Damon Conover whose telephone number is (571) 272-5448. The examiner can normally be reached Monday – Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta, can be reached at (571) 272-7453. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Application/Control Number: 10/626,028 Page 16

Art Unit: 2624

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